Review of Cardiovascular Disease Risk in HIV Treatment

Veronica Miller PhD
Forum for Collaborative HIV Research
**Forum Mission**

- The Forum for Collaborative HIV Research is a public/private partnership including government agencies, industry, HIV researchers and clinicians, payors, foundations and the HIV patient advocacy community.

Our mission is to facilitate and enhance HIV research.
History of FCHR Work on Metabolic Abnormalities and Cardiovascular Risk

1998

1998-2000

1998-2004

Metabolic Abnormalities & Consequences

Mitochondrial Tox, Bone; Adipocytes

Cardiovascular Risk Review*

Regulatory Considerations in Rx of Lipodystrophy


*with support from HAART Oversight Committee

V Miller June 2010

www.hivforum.org
Late 1990’s: Emerging Fat Redistribution Syndrome

- Lipodystrophy
- Series of roundtables*:
  - Metabolic abnormalities and consequences
- Discussions led to design and implementation of the FRAM Study (The Study of Fat Redistribution and Metabolic Change in HIV Infection)

*http://www.hivforum.org/index.php?option=com_content&task=view&id=205&Itemid=102

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2004: Regulatory Considerations for Treatment of Lipodystrophy

- **Goals:**
  - recommend methods of objective and subjective measurement
  - recommend entry criteria for clinical trials based on the type of lipodystrophy
  - recommend the degree and duration of response that would merit regulatory approval of a treatment or intervention
  - assess any additional endpoints that might be required for the approval of a treatment intervention

- **Recommendations applied in FDA review of tesamorilin for the treatment of excess abdominal fat in HIV patients with lipodystrophy**

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Cardiovascular Risk in HIV Infection & Treatment 2010

- A series of Forum roundtables addressing:
  - Statistical issues
  - Biologic mechanisms
  - Clinical impact
- Public workshop
- Satellite symposium @ International AIDS Conference in Vienna
Project Steering Committee

- Kendall Markus (FDA) (Co-chair RT#1)
- Judy Aberg (FCHR EC)
- Dominique Costagliola
- Courtney Fletcher
- Filip Josephson (EMA)
- Amy Keller (FCHR)
- Veronica Miller (FCHR)
- Neil Poulter
- Peter Reiss
- Heather Ribaudo (ACTG)
- Caroline Sabin
- Neil Shortman (HAART Oversight Committee)
- Jur Strobos (FCHR)
- Jeff Taylor
- Russ Tracy
Support Acknowledgment

- Abbott
- Gilead
- HAART Oversight Committee
- Pfizer
- Tibotec
- ViiV
Today’s Agenda

• Introduction, Goals & Objectives and Perspectives
• Summary of roundtables
• Panels
  - Pathophysiology
  - Understanding Observational Database Analysis
  - Clinical Implications
**Introductions: Panel Moderators**

- Jur Strobos MD JD (FCHR since Jan 2010)
  - Previously served as Director of Policy Research in the Office of the Commissioner FDA
  - More than 30 years of experience working in patient health care, clinical research, and international drug regulation.
    - drug law, clinical study design and good manufacturing practices
Introductions: Panel Moderators

- Ralph D’Agostino Sr. (Boston University)
  - Chair Mathematics and Statistics Department
  - Director, Framingham Study: Statistics/Data Management
  - Statistical Consultant, New England Journal of Medicine
  - Editor, Statistics in Medicine
  - Editor, Encyclopedia of Clinical Trials
Introductions: Panel Moderators

- Wendy Post MD MS (Johns Hopkins University)
  - Associate Professor of Medicine Div of Cardiology
  - Cardiologist JH Ciccarone Center for Prevention of Heart Disease and Echocardiography Laboratory
  - Principal Investigator MESA (Multi-Ethnic Study of Atherosclerosis)
  - PI Subclinical Vascular Disease and Metabolic Abnormalities in MACS
Some Rules to Follow Today

• Sessions are being web-cast
  – Speak into microphones
  – Identify yourself when asking questions
  – Alternatively can submit question by handwriting and passing forward to panel

• Panel Sessions
  – Each panelist will start with brief comments
  – Audience participation expected in discussion
Introductions: Session 1

- Filip Josephson MD PhD
  - EMA
- Bob Munk PhD
  - AIDS InfoNet
- Neil Shortman
  - HAART Oversight Committee; ViiV
- Kendall Marcus
  - FDA